UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,847	03/30/2001	Peter J. Sims	26336-23	7002

7590 02/25/2003

Raymond A. Miller
c/c Pepper Hamilton LLP
500 Grant Street
50th Floor
Pittsburg, PA 15219-2502

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	17

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,847	SIMS ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-34 and 59-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-34 and 59-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 15, applicant canceled claims 1-25, 35-58, amended claims 26, 29, 30, 34 and added new claims 59-67. Claims 26-34 and 59-67 are under consideration. The amendment to the first paragraph of the specification presented in paper no. 16 is also acknowledged and accepted.

Election/Restrictions

SEQ ID NO: 1 in newly submitted claim 65 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim requires that the Phospholipid Scramblase polypeptide has the amino acid sequence as set forth in SEQ ID NO: 1 and SEQ ID NO: 2. SEQ ID NO: 1 was not searched or considered with the elected group, drawn to a method of inhibiting or preventing a viral infection by introduction of a polypeptide (emphasis added). SEQ ID NO: 1 is a polynucleotide and is not a polypeptide. In addition, the elected amino acid sequence of SEQ ID NO: 2 is distinct from a polynucleotide because the sequences comprise different residue structures, functions and molecular weights. These distinct characteristics require a separate and divergent search for each SEQ ID NO.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, SEQ ID NO: 1 of claim 65 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 59-67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claims 26-34, respectively. Applicant

is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Newly presented claims 59-67 are drawn to a method of preventing viral infection by introducing a Phospholipid Scramblase polypeptide or fragment into a cell, while claims 26-34 are drawn to method of inhibiting viral infection by introducing a Phospholipid Scramblase polypeptide or fragment into cells. "Inhibiting" and "preventing" viral infection is not distinguishable, as each verb is drawn to prophylactic intervention. Also, claims 26-34 require introducing the instant polypeptide into cells to inhibit viral infection, while claims 59-67 are drawn to introducing the same polypeptide into a cell (emphasis added). The original claim set (26-34) encompasses introduction of the polypeptide into individual cells within a population. Therefore, the introduction of the polypeptide into individual cells in claims 59-67, fails to further limit the subject matter of claims 26-34, respectively.

Because newly presented claims 59-67 encompass the same subject matter for reasons discussed above, any rejections that still apply to claims 26-34, maintained for reasons of record, are also applied against claims 59-67.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 30, 34, 62, 63 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 62 are confusing because it cannot be determined what is intended by the phrase, "the viral infection functions". The claims are also confusing because cells do not contain membrane envelopes and it cannot be discerned how these cell membrane envelopes are derived.

Claims 30 and 34 recite the limitation "polypeptides and fragments" in lines 2 of claim 30 and lines 2 and 4 of claim 34 and claims 63 and 67 recite the limitation " polypeptides" in line 2 of each claim. There is insufficient antecedent basis for these limitations in the claims.

Claims 34 and 67 are drawn to fragment peptidomimetics of Phospholipid Scramblase polypeptide. The amendment to claim 34 does not clarify whether the fragments are mimicking the structure or function of the claimed polypeptide and the rejection is maintained for reasons of record.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-34 and 59-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection, maintained for reasons of record.

Applicant states that the viral infection referred to in the claims is only drawn to those viruses associated with the cell membrane.

Applicant's statement has been carefully considered in view of the claims. Claims 26-28, 30-34, 59-61 and 63-67 are drawn to preventing/inhibiting viral infection. This recitation in the claims does not limit virus type, mode of transmission, infectivity or pathology.

Applicant also asserts that there are numerous examples of the Phospholipid Scramblase genus containing the instant motif throughout the disclosure as well as scientific support that the skilled artisan would expect fragments comprising the motif to function similarly. Applicant also states that the skilled artisan would be able to make the polypeptides having the required activity.

Applicant's arguments have been carefully considered, but are found unpersuasive. Although applicant asserts that the disclosure cites numerous examples of enzymes containing the motif, applicant has not pointed to a specific fragment within the disclosure containing the instant motif that retains the required function and the examiner is unable to locate one. Therefore, it is determined that the specification does not disclose representative fragments of the genus claimed comprising the instant PPxY motif that would bind to every WW motif within target proteins to prevent viral infection. Contrary to applicant's assertions, it is maintained that the skilled artisan would be unable to make the instant polypeptides because the specification does not teach how the skilled artisan could identify any possible fragment of Phospholipid Scramblase with the required sequence motif that retains the required activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not convey possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemi chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 26-34 and 59-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record incorporated herein.

Applicant states that the rejection should be withdrawn because the claims are limited to virus-budding viral infections. However, as discussed above, claims 26-28, 30-34, 59-61 and 63-67 are not limited to virus type, mode of transmission, infectivity or pathology. Applicant's assertion does not remedy the lack of art-recognized animal models of HIV and Ebola infections to determine the effectiveness of the instant polypeptide or fragments on viral infectivity.

In response to the concern for effectively delivering the instant polypeptide, applicant asserts that well known means of delivery are described in the specification, such as transferring DNA expressing the protein into cells. However, this assertion does not obviate the unpredictability of determining what effect the instant enzyme will have on normal cellular function. This concern is also admitted in the instant disclosure on page 64. This lack of unpredictability stems from the fact that the function of this enzyme has not been clearly defined in the specification or in the art; see the teachings of Sims et al., cited in the previous Office action. There is also a lack of working examples drawn to effective delivery.

Applicant also states that the disclosure teaches how to determine antiviral function without an undue quantity of experimentation. However, the claims are also drawn to fragments comprising a motif that inhibits/prevents all viral infection. The disclosure does not teach a representative number of the species claimed. Therefore, the skilled artisan would be able to make the scope of the claimed genus because the species are structurally unrecognizable.

Applicant discusses the results of example 4 and concludes that IFN-β and Hu-PLSCR1 have a synergistic effect on the reduction of virus yield. Applicant's discussion is appreciated. However, due relative slight reduction of viral yield with the enzyme alone and the synergistic effect of cytokine and enzyme on viral yield, it is maintained that the results are ambiguous for whether the cytokine or the enzyme had a direct effect on VSV replication. Also, there is no example demonstrating inhibition/prevention of viral infectivity. For these reasons, the rejection is maintained for reasons of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
February 22, 2003

JAMES HOUSEL 2/23/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600